



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,847	05/14/2001	Brian Mathur	LEX-0173-USA	8347

24231 7590 04/22/2003

LEXICON GENETICS INCORPORATED
8800 TECHNOLOGY FOREST PLACE
THE WOODLANDS, TX 77381-1160

EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
----------	--------------

1631

DATE MAILED: 04/22/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/854,847

Applicant(s)

MATHUR ET AL.

Examiner

Carolyn L Smith

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5 and 6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,5 and 6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 2, 3, 5, and 6 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicant's amendments and remarks, including the cancellation of claims 1 and 4, the amendment of claim 2, and the addition of claims 5 and 6, as well as the request for reconsideration in Paper No. 12, filed 2/28/03, are acknowledged.

Applicant's arguments, filed 2/28/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 2 (amended), 3, 5 (new), and 6 (new) are herein under examination.

Claims Rejected Under 35 U.S.C. § 101

Lack of Patentable Utility

The rejection of claims 2 and 3 is maintained and presently applied to new claims 5 and 6 under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either a specific and/or substantial utility or a well-established utility.

The rejection is reiterated from the previous Office action and maintained for reasons of record.

Applicants argue that the Action seems to be implying that due to the potential novelty of the claimed sequence of SEQ ID NO: 2, that this is implying it lacks utility. This is found unpersuasive because the previous Office action does not imply the lack of utility for this reason. Instead, the previous Office action stated that insufficient evidence was provided to affirm the presence of specific and substantial utility. Applicants state previous patents to compare their

utility; however, every patent is examined individually relying on its own fact pattern.

Applicants state various case law and the idea that the legal test for utility involves an assessment of the credibility or believability of the invention. This is found unpersuasive because the guidelines Examiners use to determine patentable utility include specific, substantial, and credible, or well-established utilities as set forth in the previous Office action. Applicants state the potential business and economical use of human genome sequences as a form of utility; however, this is found unpersuasive because businesses investing billions of dollars in such practices are directed to massive database evaluation and not to individual sequences, such as those claimed in the instant invention.

Applicants argue that the SEQ ID NO: 2 (including a polynucleotide encoding it, expression vectors and cells containing it) has utility by assessing gene expression patterns using high-throughput DNA chips (Applicants' Response Paper No. 12, page 6, lines 16-18 and specification, page 5, lines 26-29). However, the specification does not disclose any specific association of any specific gene expression pattern obtained with the claimed SEQ ID NO: 2 with any real world utility. Further research would be required to determine real world utilities for the assessed gene expression pattern. Thus, the nucleic acid does not have a readily applicable real world utility. Applicants assert generically that the present sequence can treat diseases and disorders (page 1, lines 12-23), but fail to provide a specific disease with which SEQ ID NO: 2 is associated.

Applicants argue evidence of specific utility of the sequences of the present invention by identifying functionally active intron/exon splice junctions based on results of a BLAST analysis using SEQ ID NO: 1 to find comparative sequences, such as GenBank accession numbers

Art Unit: 1631

BC035124, BD027333, and AL355987. This is found unpersuasive as a specific utility as this homology to other sequences still does not provide a utility that would be specific to the sequence being claimed.

Therefore, the nucleic acid that encodes SEQ ID NO: 2, the recombinant expression vector, and the cell comprising the same do not have a readily applicable real world utility.

Claims Rejected Under 35 U.S.C. 112, First paragraph

Lack of Enablement

The rejection of claims 2 and 3 are maintained and presently applied to new claims 5 and 6 under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility, or alternatively, a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

Applicants state their reasoning for utility expressed in Part IV of their response overcomes the 35 U.S.C. § 112, first paragraph enablement rejections. The arguments presented in Part IV were found unpersuasive so that the 35 U.S.C. § 112, first paragraph, enablement rejections are hereby maintained.

Lack of Written Description

The rejection of claims 2 and 3 is maintained and presently applied to claims 5 and 6 (due to their direct or indirect dependency from claim 3) under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

Art Unit: 1631

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants submit on page 10, line 18, that claims 2 and 3 read on full length sequences. Amending claims 2 and 3 to clarify that nucleotide sequence encodes “the *entire* amino acid sequence” would nullify this lack of written description rejection. This amendment would clarify that *no* other amino acid sequences, such as fragments, are included which fail to meet the written description provisions of 35 USC 112, first paragraph.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claim 3 is maintained and presently applied to new claims 5 and 6 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 3 recites the phrase “encodes *the* amino acid sequence” which is vague and indefinite, because it is unclear if the nucleic acid encodes the entire amino acid sequence or just a fragment of the sequence. While Applicants state in their response, filed 2/28/03, that this phrase reads on a molecule that encodes the full-length of SEQ ID NO: 2, it is maintained that this is not *necessarily* the only interpretation of the reading of the phrase. Claims 5 and 6 are also rejected due to their direct or indirect dependence from claim 3. Amending the claim to

read “the *entire* amino acid sequence” would nullify this 35 U.S.C. 112, second paragraph, rejection.

Claim Rejections – 35 USC §102

The rejection of claims 2 and 3 are maintained and presently applied to claims 5 and 6 under 35 U.S.C. 102(e)(2) as being anticipated by Xu (P/N 6,284,241).

Applicants allege that while SEQ ID NO: 52 of Xu might hybridize under highly stringent conditions to SEQ ID NO: 1 or the full complement thereof of the instant invention, it would not encode the amino acid sequence of SEQ ID NO: 2. However, claims 2 and 3 state nothing regarding whether the nucleic acid molecule would need to encode the amino acid sequence in its entirety or only a fragment. Applicants address the encoding of the entire amino acid sequence; however, claims 2 and 3 as written do not specifically state this entirety.

Xu discloses recombinant expression vectors and host cells comprising the inventive polynucleotide molecules, such as SEQ ID NO: 52 (col. 2, lines 7-11 and col. 7, lines 20-24).

Therefore, Xu anticipates claims 2, 3, 5, and 6.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

Art Unit: 1631

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

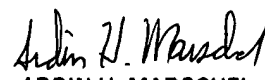
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

April 14, 2003


ARDIN H. MARSCHEL
PRIMARY EXAMINER